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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,561	11/30/2001	Keiichi Yokoyama	216547US0CONT	3792
22850	7590	06/15/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER

1653

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/996,561

**Applicant(s)**

YOKOYAMA ET AL.

**Examiner**

Samuel W Liu

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-53 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-53 is/are rejected.
- 7) ☒ Claim(s) 28-32 and 49-53 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/1/03, 4/16/02 &amp;</u> | 6) <input type="checkbox"/> Other: _____  |

***DETAILED ACTION***

*Status of the claims*

Claims 26-53 are pending.

Applicants' preliminary amendment filed 30 November 2001, which cancels claims 1-25 and adds claims 26-53 have been entered.

The pending claims 26-53 are examined in this Office action.

***IDS***

The references lists in IDS filed 1 April 2003 and IDS filed 16 April 2002 have been considered by Examiner.

Please note that Applicants' submission of the IDS filed 30 November 2001 is incomplete since it contains no copies of foreign patent documents and non-patent literatures listed in PTO 1449 forms of said IDS. Yet, note that Examiner has reviewed and considered all cited US Patent documents in page 1 of the IDS. The instant application fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. The information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any items of information contained in this information disclosure statement or the submission of any missing items will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C (1).

***Specification/Claim/ Objections***

The disclosure is objected to because of the following informalities:

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In page 1 of the specification, which was amended by applicants' preliminary amendment filed 30 November 2001, after "...U.S. Application Serial No. 09/448,310 filed November 24, 1999", delete "now allowed" and insert ", now US Patent No. 6538122".

In page 8, line 9, "SEQ ID No. 1" should be changed to "SEQ ID NO:1". The same change should be made throughout the specification.

In page 8, line 25, the specification recites "Ser-Asp-Asp-Arg-Val" a penta-peptide. Note the absence of "SEQ ID NO:\_" for this peptide sequence. In the sequence listing of the instant application, this peptide is designated "SEQ ID NO:60" (see page 18 of the sequence listing). Thus, "SEQ ID NO:60" should be inserted after "Ser-Asp-Asp-Arg-Val". The similar change should be made throughout the specification.

In claim 28, lines 1 and 3, "encoding for" should be changed to "encoding". See also claims 29 and 49-51.

In claim 29, after "Ser-Asp-Asp-Arg-Val", "(SEQ ID NO:60)" should be inserted.

In claim 30, after "Ser-Asp-Asp-Arg-Val" and "TCTGACGATCGTGTT", "(SEQ ID NO:60)" and "(SEQ ID NO:61)" should be inserted, respectively; after "the N-terminal amino acid", "(serine)" should be inserted. See also claims 30-32 and 49-53.

Claim 31 is objected to as non-compliant with 37 C.F.R. 1.821 (d). The "SEQ ID NO:\_" is missing from the claim for the amino acid sequence "Thr-Pro-Pro-Ala". Correction is required. A new paper copy and a computer readable form (CRF) are required as is the statement regarding no new matter and that the paper and CRF copies are identical. The period for response to this objection is the same as the period for response to this Office action and runs from the mailing date of this Office action. See also claims 32 and 52.

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In claim 49, "SEQ ID No. 1" should be changed to "SEQ ID NO:1".

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26-53 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claim 26 and the dependent claims thereto, as written, do not sufficiently distinguish over nucleic acids, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

***Claim Rejection, 35 U.S.C. 101, Double Patenting***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *See Miller v. Eagle Mfg. Co.*,

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151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47 and 48 are rejected under 35 U.S.C. 101 as claiming the same invention as claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22 and 23 of prior U.S. Patent No.6013498.

Claims 49, 50, 51, 52 and 53 are rejected under 35 U.S.C. 101 as claiming the same invention as claims 1, 2, 3, 4 and 5 of prior U.S. Patent No.6538122 because they are identical in words to words.

### ***Conclusion***

No claims are allowed.

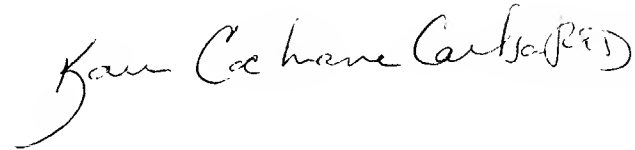
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after

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final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu, Ph.D.  
Art Unit 1653, Examiner  
June 3, 2004



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER